

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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2004 APR 27 A 10:45

FITZPATRICK, CELLA, HARPER & SCINTO  
WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year)	23/04/2004
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Applicant's or agent's file reference <b>000005.1205PC</b>	REPLY DUE within 2 / 00 months/days from the above date of mailing
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International application No. <b>PCT/US03/26644</b>	International filing date (day/month/year) <b>27/08/2003</b>	Priority date (day/month/year) <b>30/08/2002</b>
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International Patent Classification (IPC) or both national classification and IPC <b>A61K31/522</b>
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Applicant <b>KYOWA HAKKO KOGYO CO. LTD. et al.</b>
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1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I  Basis of the opinion
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- IV  Lack of unity of invention

- V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

- VI  Certain documents cited

- VII  Certain defects in the international application

- VIII  Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.  
For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **30/12/2004**

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Examiner  Formalities officer (incl. extension of time limits) Tel. (+49-89) 2399 2828
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**I. Basis of the opinion**

The basis of this written opinion is the application as originally filed.

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been and will not be the subject of the international preliminary examination in respect of the claims which have not been searched (Article 17(2)(a) or (3) and Rule 66.1(e) PCT; see also international search report).

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

1. To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out:
  2. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims, which have been the subject of an international search report, does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claim references).
  3. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

**NB:** Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.